



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

Re: Protonix  
Docket No. 00E-1348

The Honorable James. E. Rogan  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
Box Pat. Ext.  
P.O. Box 2327  
Arlington, VA 22202

MAR 10 2003

Dear Director Rogan:

This is in regard to the patent term extension application for U.S. Patent No. 4,758,579 filed by BYK Gulden Lomerg Chemische Fabrik GmbH under 35 U.S.C. § 156. The patent claims Protonix (pantoprazole sodium), NDA 20-987.

In the July 16, 2002, issue of the Federal Register (67 Fed. Reg. 46681), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before January 13, 2003, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Charles E. Van Horn  
Finnegan, Henderson, Farabow, Dunner & Garrett  
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Washington, DC 20005-3315